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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,567	07/22/2003	Sunghoon Kim	012679-093	6562

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EXAMINER

LEE, BETTY L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/623,567	Applicant(s) KIM, SUNGHOON	
	Examiner Betty Lee, Ph.D.	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed December 27, 2005 is acknowledged. Claims 1-9 are pending and under examination. The text of those sections of Title 35 U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

The objection to the Abstract is withdrawn in view of the current amendment.

The objection to Claim 9 as lacking an antecedent basis for the term "dermatitis" is withdrawn in view of the current amendment.

Claim Rejections - 35 USC § 112

The rejection of claims 1-9 under 35 U.S.C. 112 is withdrawn pursuant to Applicant's amendment of 12/27/2005, and arguments, which were persuasive.

Claim Rejections Maintained

Claim Rejections - 35 USC § 103

The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over Kim, *et al.* in view of Gallucci, *et al.* is maintained for reasons of record in the Office Action of 9/27/2005. Applicant's arguments filed 12/27/2005 have been fully considered but are not deemed to be persuasive.

Applicant argues that the Office is using hindsight to stretch the teachings of Gallucci, *et al.* to fit its conclusion. Applicant asserts that the cited documents are selectively interpreted to fit the invention.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It is well known in the art that cytokines such as IL-6 and growth factors are involved in wound healing. In addition, Kim, et al. teach that p43 promotes wound healing and has cytokine activity. Therefore, it would be *prima facie* obvious that the polypeptide of the instant application which is 100% identical to p43 would have wound healing activity. Applicant asserts that Gallucci, et al. teach that transfer of rmIL-6 into IL-6 KO mice produced only a reversal of the healing deficiency of IL-6KO mice and do not teach that IL-6 actually stimulates wound healing, particularly in an IL-6 normal background. In response to Applicant's assertions, RT-PCR results confirmed IL-6 expression only in those mice that healed and lack of expression in those that displayed impaired healing (pg 2528, col 2). Applicant asserts that Gallucci, et al. suggest only that IL-6 is a cytokine associated with wound healing to the extent that its absence causes a deficiency in healing and that there is no experimental data to show whether the wound healing would be promoted in a case where wounded wild-type mice are treated with IL-6. Applicant further asserts that a person of ordinary skill in the art would

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not know whether IL-6 could indirectly promote wound healing after reading Gallucci, *et al.*

In response to Applicant's assertions, Gallucci, *et al.* suggest that IL-6 is intimately involved in cutaneous wound healing, as IL6 KO mice display impaired wound healing manifested as deficiencies in re-epithelization, granulation tissue formation and inflammation (pg 2529, col 2). In addition, rmlL6 can augment wound healing and a potential therapeutic for side effects associated with immunosuppressive therapy (pg 2530, col 1). Gallucci, *et al.* teach that in the absence of IL-6, deficiency in healing occurs. Therefore, the presence of IL-6 will stimulate healing. Applicant argues that the relevance of Gallucci, *et al.* is negated because IL-6 is not related to the effect of p43. Applicant further asserts that p43 is a precursor of EMAP II and EMAP II has a cytokine activity as taught by Kim, *et al.* Applicant asserts that experimental data shows that p43 has both cytokine activity and the effect on stimulation of wound healing, while EMAP II has cytokine activity and no effect on wound stimulation.

In response to Applicant's assertions, EMAP II is the C-terminal domain of p43. The polypeptide of the instant application is 100% homologous to p43 and would then be expected to have the same intrinsic properties of p43, including stimulation of wound healing. Furthermore, WO 01/9927 teaches on p. 6 and in figure 4 that p43 and EMAP II stimulate IL-6 release, thus, clearly, the action of p43 is related to that of IL-6 and the artisan would expect results similar to those obtained with IL-6.

The rejection of claims 2-9 under 35 U.S.C. 103(a) as being unpatentable over Kim, *et al.* in view of Gallucci, *et al.* and further in view of Bennett, *et al.* is maintained

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for reasons of record in the Office Action of 9/27/2005. Applicant's arguments have been fully considered but are not deemed to be persuasive.

Applicant argues that Bennett, *et al.* do not provide further teaching that would provide a suggestion to combine Kim, *et al.* with Gallucci, *et al.* or a reasonable expectation of success that the proposed combination would be successful.

In response to Applicant's arguments, the fact that Bennett, *et al.* teach that growth factors accelerate healing of epidermal injuries would be sufficient motivation to combine the use of growth factors with the polypeptide of Kim, *et al.* for stimulating wound healing as taught by Gallucci, *et al.*

The rejection of claims 1, 4 and 7 under 35 U.S.C. 103(a) as being unpatentable over Kim, *et al.* in view of Gallucci, *et al.* and further in view of Goddard, *et al.* is maintained for reasons of record in the Office Action of 9/27/2005. Applicant's arguments have been fully considered but are not deemed to be persuasive.

Applicant argues that Goddard, *et al.* do not cure the deficiencies of Kim, *et al.* and Gallucci, *et al.* and provide no further teaching to provide a suggestion to combine Kim, *et al.* and Gallucci, *et al.* or a reasonable expectation of success.

In response to Applicant's arguments, Goddard, *et al.* teach the use of the growth factor VEGF for treating subcutaneous wounds and diabetic ulcers. The person of ordinary skill in the art at the time in the invention was made would have been motivated to treat ulcers as taught by Goddard, *et al.* with the polypeptide of Kim, *et al.* Furthermore, the person of ordinary skill in the art would be motivated to administer the

composition comprising of the growth factor and the polypeptide of the instant application as ointments, creams, gels or suspensions as taught by Goddard, *et al.*

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Lee, Ph.D. whose telephone number is (571) 272-8152. The examiner can normally be reached on M-F 9 am-5: 30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BLL


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER